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NOTICE OF ALLOWANCE AND FEE(S) DUE

7590

09/23/2003

ANTOINETTE F KONSKI ESQ McCUTCHEN, DOYLE, BROWN & ENERSEN, LLP Three Embaracadero Center Suite 1800 San Francisco, CA 94111 EXAMINER

NGUYEN, DAVE TRONG

ART UNIT CLASS-SUBCLASS

1632 424-450000

DATE MAILED: 09/23/2002

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/434.345	11/05/1999	TENI BOULIKAS		3841

TITLE OF INVENTION: THERAPY FOR HUMAN CANCERS USING CISPLATIN AND OTHER DRUGS OR GENES ENCAPSULATED INTO LIPOSOMES

ſ	APPLN. TYPE	SMALL ENTITY	ISSUE FEÉ	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
	nonprovisional	YES	\$640	\$0	\$640	12/23/2002

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. <u>PROSECUTION ON THE MERITS IS CLOSED.</u> THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN <u>THREE MONTHS</u> FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. <u>THIS STATUTORY PERIOD CANNOT BE EXTENDED</u>. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

- A. Pay TOTAL FEE(S) DUE shown above, or
- B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.
- ☐ Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

II. PART B = FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.



PART B - FEE(S) TRANSMITTAL



Complete and send this form, together with applicable fee(s), to: Mail Box ISSUE FEE

Commissioner for Patents Washington, D.C. 20231

(703)746-4000 Fax

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks I through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block I, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for

maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1) Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. 09/23/2002 ANTOINETTE F KONSKI ESQ McCUTCHEN, DOYLE, BROWN & ENERSEN, LLP Certificate of Mailing or Transmission I hereby certify that this Fec(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above, or being facsimile transmitted to the USPTO, on the date indicated below. Three Embaracadero Center Suite 1800 San Francisco, CA 94111 (Depositor's name (Signature (Date APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 11/05/1999 TENI BOULIKAS 3841 09/434.345 TITLE OF INVENTION: THERAPY FOR HUMAN CANCERS USING CISPLATIN AND OTHER DRUGS OR GENES ENCAPSULATED INTO LIPOSOMES APPLN. TYPE SMALL ENTITY **ISSUE FEE PUBLICATION FEE** TOTAL FEE(S) DUE DATE DUE \$640 12/23/2002 nonprovisional YES \$0 \$640 EXAMINER ART UNIT CLASS-SUBCLASS NGUYEN, DAVE TRONG 1632 424-450000 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a $\ensuremath{\square}$ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. single firm (having as a member a registered ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment. (B) RESIDENCE: (CITY and STATE OR COUNTRY) (A) NAME OF ASSIGNEE Please check the appropriate assignee category or categories (will not be printed on the patent) ☐ individual ☐ corporation or other private group entity ☐ government 4a. The following fee(s) are enclosed: 4b. Payment of Fee(s): ☐ A check in the amount of the fee(s) is enclosed. ☐ Issue Fee ☐ Payment by credit card. Form PTO-2038 is attached. ☐ Publication Fee ☐ The Commissioner is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number ______(enclose an extra copy of this form). ☐ Advance Order - # of Copies Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above. (Authorized Signature) (Date) NOTE; The Issue Fee and Publication Fee (if required) will not be accepted from anyone

other than the applicant; a registered attorney or agent; or the assignee or oth interest as shown by the records of the United States Patent and Trademark Office.

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, D.C 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/434,345	11/05/1999	TENI BOULIKAS		3841
75	90 09/23/2002		EXAMIN	ER
ANTOINETTE F KONSKI ESQ McCUTCHEN, DOYLE, BROWN & ENERSEN, LLP Three Embaracadero Center			NGUYEN, DAVE TRONG	
			ART UNIT	PAPER NUMBER
Suite 1800	Suite 1800 San Francisco, CA 94111			
UNITED STATES			DATE MAILED: 09/23/2002	

Determination of Patent Term Extension under 35 U.S.C. 154 (b) (application filed after June 7, 1995 but prior to May 29, 2000)

The patent term extension is 0 days. Any patent to issue from the above identified application will include an indication of the 0 day extension on the front page.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (http://pair.uspto.gov)



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7590 09/23/2002			EXAMINER		
ANTOINETTE I	_	NGUYEN, DAVE TRONG			
McCUTCHEN, DOYLE, BROWN & ENERSEN, LLP Three Embaracadero Center			ART UNIT	PAPER NUMBER	
Suite 1800	04111		1632		
San Francisco, CA 94111 UNITED STATES			DATE MAILED: 09/23/2002		

Notice of Possible Fee Increase on October 1, 2002

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after October 1, 2002, then the amount due may be higher than that set forth in the "Notice of Allowance and Fee(s) Due" since there may be an increase in fees effective on October 1, 2002. See Revision of Patent and Trademark Fees for Fiscal Year 2003; Notice of Proposed Rulemaking, 67 Fed. Reg. 30634, 30636 (May 7, 2002). Although a change to the amount of the publication fee is not currently proposed for October 2002, if the issue fee or publication fee is to be paid on or after October 1, 2002, applicant should check the USPTO web site for the current fees before submitting the payment. The USPTO Internet address for the fee schedule is: http://www.uspto.gov/main/howtofees.htm.

If the issue fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due," but not the correct amount in view of any fee increase, a "Notice to Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice to Pay Balance of Issue Fee," if the response to the Notice of Allowance and Fee(s) due form is to be filed on or after October 1, 2002 (or mailed with a certificate of mailing on or after October 1, 2002), the issue fee paid should be the fee that is required at the time the fee is paid. If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously paid issue fee should be paid. See Manual of Patent Examining Procedure, Section 1308.01 (Eighth Edition, August 2001).

Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

Notice of Allowability Dave Neguyen	•	Application No.	Applicant(s)		
Examiner	, , , , , , , , , , , , , , , , , , , ,	09/434 345	ROULIKAS TENI		
- The MAILING DATE of this communication appears on the cover sheet with the correspondence address-All claims being allowable, PROSECUTION ON THE MERTIS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-86) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CRT 1.313 and MPEP 1308. 1. ☑ This communication is responsive to 07/01/02. 2. ☑ The allowed claim(s) is/are 1-23 and 27-22. 3. ☐ The drawings filed on	Notice of Allowability				
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3. ☐ The drawings filed on are accepted by the Examiner. 4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some* o) ☐ None of the: 1. ☐ Certified copies of the priority documents have been received. 2. ☐ Certified copies of the priority documents have been received in Application No 3. ☐ Copies of the certified copies of the priority documents have been received in Application No 4. ☐ Certified copies not received: 5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). (a) ☐ The translation of the foreign language provisional application has been received. 6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 120 and/or 121. Applicant has THREE MONTHS FROM THE *MAILING DATE* of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. 8. ☐ CORRECTED DRAWINGS must be submitted. (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) ☐ hereto or 2) ☐ to Paper No. § Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson. 9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding Requirement (PTO-148), Paper No. 15. 10. Notice of Informal Patent Application (PTO-152) information Disclosure Statements (PTO-143), Paper No. 15. 11. ACCOSS SCRIVENS PATENT	All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in this ap or other appropriate communication GHTS. This application is subject t	plication. If not included n will be mailed in due course, THIS		
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below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS must be submitted. (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No. 8. (b) including changes required by the proposed drawing correction filed (c) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL Attachment(s) DEPOSIT OF References Cited (PTO-892) Notice of References Cited (PTO-892) Notice of Draftperson's Patent Drawing Review (PTO-948) Information Disclosure Statements (PTO-1449), Paper No. 15. Examiner's Comment Regarding Requirement for Deposit of Biological Material DANNECE M. JACOSS SCRIVENS PATENT ANALYST	6. Acknowledgment is made of a claim for domestic priority ur	nder 35 U.S.C. §§ 120 and/or 121.			
INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. 8.	Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.				
(a) ☑ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) ☐ hereto or 2) ☑ to Paper No. 8. (b) ☐ including changes required by the proposed drawing correction filed, which has been approved by the Examiner. (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson. 9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Attachment(s) 1☐ Notice of References Cited (PTO-892) 3☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5☐ Information Disclosure Statements (PTO-1449), Paper No. 15. 1☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material 2☐ Notice of Informal Patent Application (PTO-152) 4☐ Interview Summary (PTO-413), Paper No 6☐ Examiner's Statement of Reasons for Allowance of Biological Material 2☐ Other 2☐ Notice of Informal Patent Application (PTO-152) 4☐ Interview Summary (PTO-413), Paper No 6☐ Examiner's Statement of Reasons for Allowance of Biological Material					
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The specification has been amended, claims 1, 10, 15-22, and 28 have been amended by the amendment after final dated July 1, 2002.

Upon a further consideration of the subject matter being sought in non-elected claims 27 and 28, the restriction requirement between claims 27, 28 and the presently pending elected claimed invention has been withdrawn by the examiner. Thus, claims 27 and 28 have been rejoined to the elected claimed invention.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Konskie on September 18, 2002. The examiner further indicated to applicant's representative that all presently pending claims are allowed in view of the examiner's amendment so as to clarify the proper antecedent basis intended for the claims. Note that claim 2 has been amended to be consistent with the amended language as cited in the amended claim 1.

The claims have been amended as follows:

- Claims 24-26 have been canceled.
- In claim 27, the word micelle has been added between the word "cisplatin" and the word "of".
- Claim 2 has been rewritten as follows:

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2. A method of producing cisplatin micelles, comprising:

a) combining a suitable buffer solution, cisplatin with an effective amount of at least 30% ethanol solution to form a cisplatin/ethanol solution; and

b) combining the cisplatin/ethanol solution with a negatively charged phosphatidyl glycerol lipid derivative wherein the molar ratio between cisplatin and the lipid derivative is 1:1 to 1:2, thereby producing a cisplatin mixture in its aqua form in micelles.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is (703) 305-2024.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen Primary Examiner Art Unit: 1632

> DAVET. NGUYEN PRIMARY EXAMINER

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